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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/810,872 | 03/16/2001 | Peter Zhu | JOHNA.058A | 7471 |

27777 7590 04/20/2006

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1743

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Application Number: 09/810,872
Filing Date: March 16, 2001
Appellant(s): ZHU ET AL.

MAILED
APR 20 2006
GROUP 1700

Andrew C. Farmer
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 25, 2005 appealing from the Office action mailed July 30, 2004.

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(1) Real Party In Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

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(8) Evidence Relied Upon

| | | |
|-----------|-----------|---------|
| 4,471,055 | Opp | 09-1984 |
| 4,703,763 | McAlister | 11-1987 |
| 4,521,376 | Witonsky | 06-1985 |
| 6,436,716 | Wu | 08-2002 |

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 10-12, 14 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,471,055 to Opp.

Opp teaches a process for determining whether the concentration of aldehyde in a sample is in excess of a predetermined concentration. The predetermined concentration of aldehyde is the point of interest of aldehyde. The method for determining whether aldehyde is present in a predetermined concentration taught by Opp comprises mixing the test sample with a first reaction system which reacts with carbonyl group in aldehydes, followed by reaction of the resultant product with a second reaction system, which reacts with any unreacted aldehyde, and detecting any visual formation

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of a second reaction product, as recited in claim 1 (col. 14, lines 7-41). With respect to Applicants' claimed limitation of the first reaction step occurring in the presence of the second reactant, Opp teaches at col. 3, lines 17-24 that the two reaction systems can be combined simultaneously with the sample at the beginning of the assay. The aldehydes to be tested are those used in disinfecting systems (in germicidal capacities) having at least one -CHO moiety, which includes glutaraldehyde, as recited in claims 6 and 7. The first reaction system includes reactants which form a colorless derivative of aldehyde, such as hydroxylamine or hydrazine, as recited in claim 5 (col. 4, lines 15-30). The second reaction system includes reactants that form aldehyde derivatives which are visually distinguishable from the first reaction products, such as amino acids, including glycine and lysine, as recited in claims 2-4 (col. 4, lines 38-55). Opp teaches that the first reaction products are colorless, as recited in claim 10 (col. 4, lines 15-17, col. 14, lines 42-43). With respect to claim 11, Opp teaches that the amount of first reaction system completely transform the amount of aldehyde equal to the predetermined amount, while the second reaction system provides a visual color where the amount of aldehyde exceeds the predetermined amount. Where the amount of aldehyde is less than the predetermined amount (1% for disinfecting processes), it would be inherent that no color would form since there would not be an excess amount of aldehyde to react in the second reaction system. With respect to claim 12, each of examples I-IX of Opp teaches providing a fixed volume of sample (0.1-1 milliliter) to which the reactants are added. Further, with respect to claim 14, Opp teaches that the fixed volume of test sample is added to a 7 cc reaction container (measuring device), where the reaction container contains the first reaction system reagents (hydroxylamine or hydrazine).

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b) in view of the teachings of Opp '055.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Opp in view of US Patent 4,703,763 to McAlister et al.

The disclosure of Opp is described above. Opp fails to teach loading a fixed volume of test sample into a measuring device having a liquid impermeable membrane.

McAlister et al teach a device for sample a pre-set volume of test sample. The device is a syringe-type measuring device having a plug element (filter) arranged to be air-permeable, but liquid impermeable. This allows enough fluid sample to be up taken into the syringe and then allow the fluid flow to stop when the predetermined amount is taken in. See col. 1, lines 41-59. It would have been obvious to one of ordinary skill in the art to use the device of McAlister et al to measuring an exact amount of test sample in carrying out the method of Opp. Such will prevent using excess sample. Since it is important that the amount of reagents in the method of Opp be exact for the amount of sample, using the device of McAlister et al will alleviate false positives due to incorrect reagent to sample ratios.

Therefore, for the reason set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Opp and McAlister et al.

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Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Witonsky in view of Wu.

Witonsky et al teach a method for determining whether the concentration of disinfectant/sterilant exceeds a predetermined value. The method tests for sufficient glutaraldehyde amounts in a disinfecting solution using test strips (CIDEX OPA tests for phthalaldehyde). The method involves contacting a test sample with a test strip impregnated with a sulfite compound and an amino acid compound. The sulfite compound is sodium sulfite (col. 2, line 24). The amino acid is glycine (col. 2, line 27). The method by which excess glutaraldehyde is to be determined is explained in Wu. Glutaraldehyde reacts with sulfite to form a sulfite addition product, which reacts with glycine to form sodium glycinate. Excess glutaraldehyde reacts with sodium glycinate to form a colored product. Thus, the sulfite serves as a first reactant to react with the carbonyl group in the aldehyde and sodium glycinate serves as the second reactant to react with remaining aldehyde in the sample that is unreacted. See col. 2, lines 39-52 of Wu.

Witonsky et al teaches using sodium sulfite, but fail to teach using sodium bisulfite. Wu teaches that both sodium sulfite and sodium bisulfite are effective in processes for determining the presence of aldehydes (col. 1, line 65 – col. 2, line 12). It would have been obvious to one of ordinary skill in the art to substitute sodium sulfite in Witonsky et al for sodium bisulfite, since both are known in the art to be suitable in determining the presence of aldehydes. See MPEP 2144.06.

With respect to claim 33, where Applicants recite that the first reaction step is kinetically and thermodynamically favored over the first second reaction step, such would have been obvious to the ordinarily skilled artisan because Wu teaches that aldehyde in the sample reacts with the sulfite first prior to reacting with glycine. Thus, the first reaction step would obviously have to be favored over the second reaction step.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Witonsky et al and Wu.

(10) Response to Argument

Anticipation Rejection over Opp

Appellants' arguments with respect to the anticipation rejection over Opp is not persuasive because contrary to Applicants' arguments, the Opp references does teach having a first reactant perform its reaction in the presence of a second reactant. At col. 3, lines 19-24 of Opp, the reference teaches that the two reaction systems (first reaction system which reacts with the carbonyl group in aldehydes, followed by reaction of the resultant product with a second reaction system, which reaction with any unreacted aldehydes) may be combined simultaneously with the sample at the beginning of the assay. Therefore, according to the teachings of Opp, the first reaction step may take place in the presence of the second reaction system.

Appellants' argument with respect to the teaching in Opp of shielding the second reactant until the first reaction is complete does not overcome the teaching in Opp of both reaction systems being combined simultaneously. Even though Opp teaches that the second reactant may be shielded (such as by encapsulating the second reactant), the second reactant is still "in the presence of " the first reaction, thus anticipating the claimed invention.

Obviousness Rejection over Opp in view of McAlister et al

Appellants' arguments regarding the obviousness rejection over Opp in view of McAlister et al are not persuasive. Claim 14 recites loading a fixed volume of sample to a measuring device containing the first and second reactants. Opp teaches the first and second reactants. McAlister et al contains a

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broad teaching of syringe for sampling pre-set volumes of test sample. While McAlister et al may be directed to blood sampling, the reference provides a general teaching of using syringe-type devices for loading fixed volumes of fluids in testing. The ordinarily-skilled artisan would have recognized the conventional use of syringe devices in laboratories and elsewhere during sampling and other analytical procedures.

Obviousness Rejection over Witonsky in view of Wu

Appellants' arguments regarding the obviousness rejection over Witonsky in view of Wu are not persuasive. Appellants argue that the instant invention claims only two reactions, whereas Witonsky teaches three reactions. In response the Examiner notes that reaction step disclosed in Witonsky is in fact an intermediate step (glutaldehyde reacting with sodium sulfite to produce sodium glycinate). While the claimed invention recites two reaction steps, nothing in the claims would exclude the intermediate reaction product disclosed by Witonsky. Applicants further argue that the Witonsky reference fails to teach performing the first reaction step in the presence of a compound containing an amino group. Contrarily, Wu teaches that glycine (amino-containing compound) is present in the first reaction step.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the Examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Examiner LaToya C. Younger



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